

DEC 02 2002

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510 (k) Summary

Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

Prepared: June 5, 2002

Applicant: Avanta Orthopaedics, Inc.
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San Diego, CA 92121

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Contact: Louise M. Focht

Device Name:	Wrist
Device Trade Name:	Wrist implant
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number	888.3800
Product Code:	JWJ
Predicate Device:	Universal Total Wrist System, KMI, K961051
Registration Number:	2030506
Owner Operator Number:	9001389

Device Description:

The wrist implant like the predicate device includes various sizes of implants and accessories including sizers. The implant allows for replacement of the wrist.

Indications for Use:

Avanta Orthopaedics Wrist implant is intended for replacement of the painful wrist joint due to rheumatoid arthritis, osseous arthritis, or post-traumatic arthritis.

Comparison to Predicate Device:

The legally marketed predicate device to which this device is substantially equivalent is the Universal Total Wrist System, KMI, K961051.

Table. Comparison of Avanta Orthopaedics and KMI wrist.

<i>Item</i>	<i>Avanta Product</i>	<i>KMI</i>
Product Name	Wrist Implant	KMI Universal Total Wrist System
Use	Single use	Single use
Fixation	stem in intramedullary canal, proximally Screw fixation distally	stem in intramedullary canal, proximally Screw fixation distally
Constraint	Semi-constrained	Semi-constrained
Material	Co-Cr/UHMWPE/CPTi	Co-Cr/UHMWPE/CPTi
Sizes	3 sizes small, medium, large	3 sizes small, medium, large
	Right, Left	Right, Left
Indications for use	Avanta Orthopaedics Wrist implant is intended for replacement of the painful wrist joint due to: rheumatoid arthritis, oseto-arthritis, or post-traumatic arthritis.	The KMI Universal Total Wrist System is indicated for: Intractable pain resulting from traumatic arthritis, osteo arthritis, rheumatoid arthritis, trauma induced osteo arthritis of the radial/Carpal joint. To replace functionality of the joint due to deformity of elements stated above.

Similarities of the Avanta Orthopaedics wrist implant and the KMI Universal Total Wrist System include;

Both devices are intended for single use only;

Both devices are intended for surgical implantation longer than 30 days;

Both devices are placed into the wrist joint;

Both devices are made of industry standard materials. No new materials are introduced in either product;

Both devices are comparably sized;

Both devices have the same indications for use.

Fatigue and wear testing have been performed on this devices to demonstrate substantial equivalence.

Summary:

The device and the predicate device have similar design characteristics and intended use. The new device is substantially equivalent to the predicate device.



DEC 02 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. H. Doug Plunkett
General Manager
Avanta Orthopaedics
8600 Evergreen Boulevard
Minneapolis, Minnesota 55433

Re: K021859

Trade/Device Name: Wrist Implant
Regulation Number: 21 CFR 888.3800
Regulation Name: Wrist Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWJ
Dated: August 31, 2002
Received: September 5, 2002

Dear Mr. Plunkett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. H. Doug Plunkett

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (If Known): K021859
Device Name: Wrist

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Indications for Use:

Avanta Orthopaedics Wrist implant is intended for replacement of the painful wrist joint due to rheumatoid arthritis, osseous arthritis, or post-traumatic arthritis.

(Division Sign-Off)

510(k) Number K021859

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use yes
(Per 21 CFR § 801.109)

OR

Over-the-Counter Use no
(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General Restorative
and Neurological Devices

510(k) Number K021859